

March 15, 2004

Russell A. Campbell
Compliance Officer
Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda CA 94502

Dear Mr. Campbell,

In reply to the warning letter delivered March 11, 2004:

Bianca M. Green was appointed management representative responsible for and has authority to design, implement, monitor and correct the quality system and all supporting policies and procedures within Obsidian Medical Technology. Since then, Obsidian created a Quality System Manual and associated standard operating procedures to comply with the Current Good Manufacturing Practice requirements of the Quality System Regulations for Medical Devices. The creation of all necessary documentation is not complete, but Obsidian is updating and creating databases, forms and schedules that are required. I expect the Obsidian Quality System will be complete in May 2004.

Please find the attached documentation as proof of our attempt to correct the violations that were found during Obsidian's investigation. Below you will also find explanations to the violations listed in the warning letter.

If you need assistance with any of the documentation, please do not hesitate to contact Bianca Green, Regulatory Affairs.

Best regards,

Henry E. Green
President and Chief Executive Officer

1. Violation: Management has not ensured that quality system requirements have been effectively established and maintained.

Correction: The President approved both Quality System Manual and Management Responsibility standard operating procedure. The documents ensure the quality system is established and maintained.

2. Violation: Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality as required by 21 CFR 820.20(a).

Correction: The President approved the Quality System Manual, which establishes Obsidian's policy and objectives for, and commitment to quality.

3. Violation: Failure to appoint a management representative and document such appointment.

Correction: The President approved the appointment of Bianca M. Green, Regulatory Affairs, as management representative in the Quality System Manual, 4.2.3 Management Representative.

4. Violation: Failure to conduct Management Reviews.

Correction: A schedule was established for Management Reviews in the Management Responsibility standard operating procedure. Since we are still establishing all regulations we have not had a management review.

5. Violation: Failure to establish and maintain procedure to control all documents.

Correction: A Document Control standard operating procedure was created and approved by the President and Regulatory Affairs. A log was created to keep track of all requested documents under document control.

6. Violation: Failure to adequately establish define, document and implement and maintain procedures for implementing corrective and preventive actions, which include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential cause for nonconforming product or other quality problems.

Correction: Corrective and Preventive Actions are established by the following standard operating procedures and the associated forms: Request for Action, Complaint Files, Recalls and Market Withdrawals, Quality System Nonconformity Correction and Management Responsibility. Databases and forms are required to be filled out depending on the severity of the issue.

7. Violation: Failure to adequately establish define, document and implement and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, which ensure that complaints are evaluated to determine whether the complaint represents and event which is required to be reported to FDA, Medical Device Reporting.

Correction: The following standard operating procedures were established to address complaints: Complaint Files, Field Service, Reportable Incident and Recalls and Market Withdrawals.

8. Violation: Failure of your complaint investigation to include a record of the corrective action taken.

Correction: The database that is used for complaints now requires the user to enter the corrective action that was used.

9. Violation: Failure of your complaint investigations to include a record of the name, address and telephone number of the complainant.

Correction: The database that is used for complaints now requires the user to enter the name, address and telephone number of the complainant.